

REMARKS/ARGUMENTS

This Amendment is filed in response to the Office action that was mailed on June 5, 2007. Claims 1-67 are pending in this Application. Claims 6, 10, 11, 13, 14, 26-30, 32-46, 49-53, 56-63 and 67 have been withdrawn from consideration. By this amendment, Claims 12 and 24 are amended and Claims 64-66 are canceled without prejudice. The amendments do not introduce new matter as they are fully supported by the claims, specification, and drawings as originally filed or are inherent characteristics thereof. Applicants respectfully request reconsideration and allowance of all claims in view of the following remarks.

Claim 12 was amended to correct inadvertent grammatical errors in the claim. More particularly, the term "rotable" in two places in Claim 12 was replaced with the term "rotatable." Claim 24 was amended to include the resilient material providing the roller with properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. As stated above, these amendments do not introduce new matter as they are fully supported by the claims, specification, and drawings as originally filed or are inherent characteristics thereof.

Applicants' election, without traversal, of Group I, Species 1 in reply filed on April 27, 2007 was acknowledged by the Examiner. Claims 6, 10, 11, 13, 14, 26-30, 32-36, 43-46, 49-53, 56-63 and 67 were withdrawn in the reply. The Examiner, by this Office action, has also withdrawn Claims 37-42 indicating that they are drawn to FIG. 23 and not to FIG. 3, which does not contain voids.

Claims 1-5, 7, 12, 15, 17, 18, 23, 41, 42 and 64-66 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,201,714 to Gentelia, et al.

(Gentelia `714). To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention, the prior art must be enabling, and the prior art reference must describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339 (Fed. Cir. 2000).

Regarding Claim 1, it is indicated in the Office action that Gentelia `714 discloses a trocar that is adapted to provide access for a surgical instrument through a body wall and into a body cavity. It is further indicated in the Office action that the surgical instrument of Gentelia `714 includes a cannula (3) having a proximal end and a distal end; a seal housing (2) communicating with the cannula to define a working channel (14); a seal assembly (6-11) disposed within the seal housing (2); at least one roller (6 or 7) included in the seal assembly (6-11) and having an axle (10 or 11) supported by the seal housing; and the roller having properties for forming a zero seal in the absence of the instrument (FIG. 4), and an instrument seal in the presence of the instrument (FIG. 1). Applicants respectfully traverse this rejection.

Claim 1 of the present Application includes the at least one roller having properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Applicants respectfully submit that Gentelia `714 fails to teach the roller having properties for forming an instrument seal in the presence of an instrument.

FIGURE 4 of Gentelia `714 depicts the rollers (6, 7) spring-pressed into contact with each other and into the downwardly extending block (13) to close off the passageway (14) and thus prevent the escape of pressurized gas from the abdominal

cavity (see also Gentelia `714 column 2, line 49 through column 3, line 8). In other words, FIG. 4 of Gentelia `714 depicts the rollers (6, 7) forming a zero seal when no instrument is present.

FIGURE 1 of Gentelia `714 depicts a trocar (5) passed between the spring-biased rollers (6, 7). The rollers (6, 7) are depicted as being moved from a first, contacting condition (depicted in dashed lines) to a second, separated condition (depicted in solid lines) with the trocar (5) positioned in between. In this manner, when an instrument is present the rollers (6, 7) of Gentelia `714 do not contact each other and do not form an instrument seal between the rollers (6, 7) and the instrument/trocar (5). Instead, as depicted in FIG. 1 of Gentelia `714, the rollers (6, 7) form a point contact with the instrument/trocar (5) that is not adequate to form an instrument seal.

FIGURES 3 and 5-7 of Gentelia `714 depict the device of Gentelia `714 forming the instrument seal through the use of a slidable plate (16, 26) having a small aperture (18, 28) and a large aperture (20, 27) for receiving small diameter instruments and large diameter instruments, respectively (see also Gentelia `714 column 3, lines 9-45). The small and large apertures each include an elastic diaphragm completely covering the opening and having a slit (19) therein so that when an instrument is passed through the respective aperture, the elastic diaphragm opens along the slit to permit the passage of the instrument therethrough. The elastic diaphragm forms a tight seal surrounding the instrument to prevent outflow of the pressurized gas within the abdomen (see Gentelia `714 column 3, lines 19-28). In other words, it is the diaphragms of Gentelia `714, and not the rollers, which include the properties for forming an instrument seal with instruments passed therethrough.

Based on the foregoing, Applicants respectfully submit that Claim 1 of the present Application is allowable over Gentelia '714. Applicants respectfully request that this rejection be reconsidered and removed. As Claims 2-5, 7 and 12 depend from Claim 1, Applicants respectfully submit that they are also allowable over Gentelia '714 as depending from an allowable claim. Hence, Applicants respectfully request that the rejection of Claims 2-5, 7 and 12 be reconsidered and removed.

Regarding Claim 15, it is indicated in the Office action that Gentelia '714 discloses a surgical combination comprising an instrument (5) having a diameter of at least about one millimeter; an access device (1) adapted to facilitate disposition of the instrument across a body wall; a cannula (3) included in the access device and having an axis extending between a proximal end and a distal end; a seal housing (2) communicating with the cannula, to define a working channel (14) with the cannula; a seal assembly (6-11) disposed within the seal housing (2) of the access device (1); a roller (6 or 7) included in the seal assembly, the roller being sized and configured to form a zero seal in the absence of the instrument (FIG. 4) and an instrument seal in the presence of the instrument (FIG. 1). Applicants respectfully traverse this rejection.

Similar to Claim 1 of the present Application, Claim 15 includes a roller that is sized and configured to form a zero seal in the absence of an instrument and an instrument seal in the presence of the instrument. As indicated above, Gentelia '714 fails to teach a roller that forms both a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Based on the foregoing, Applicants respectfully submit that Claim 15 of the present Application is allowable over Gentelia '714. Applicants respectfully request that the rejection of Claim 15 be

reconsidered and removed. As Claims 17, 18 and 23 depend from Claim 15, Applicants respectfully submit that they are also allowable over Gentelia '714 as depending from an allowable claim. Hence, Applicants respectfully request that the rejection of Claims 17, 18 and 23 be reconsidered and removed.

The Office action includes a rejection of Claims 41 and 42 under 35 U.S.C. § 102(b). However, as indicated in the Office Action Summary and in the Detailed Action, Claims 41 and 42 have been withdrawn by the Examiner. In a telephone conversation between Applicants' counsel and Supervisory Patent Examiner Anh Tuan Nguyen on August 20, 2007, it was indicated by Examiner Nguyen that Claims 41 and 42 should be withdrawn. By this Amendment, Claims 41 and 42 are withdrawn without traverse.

Claims 64-66 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Gentelia '714. By this Amendment, Claims 64-66 have been canceled without prejudice. Applicants respectfully submit that this rejection is now moot and respectfully request that this rejection be removed.

Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Gentelia '714. In the Office action it is indicated that Gentelia '714 discloses the invention substantially as claimed above, wherein the first roller (6) has the configuration of a first cylinder with a first radius; the second roller (7) has the configuration of a second cylinder with a second radius (FIG. 1), but fails to disclose the first axle is separated from the second axle a distance not greater than the sum of the first radius and the second radius. It is further indicated in the Office action that at the time of the invention, it would have been obvious to a person of ordinary skill in the art

to modify the valve assembly disclosed by Gentelia '714 to have the location of the axles directly at the center of the roller, separated only by the sum of the radii of the rollers, because Applicants have not disclosed in the present Specification that the axles separated only by the sum of the radii of the rollers provides an advantage, is used for a particular purpose or solves a stated problem. It is additionally indicated in the Office action that one of ordinary skill in the art would have expected Applicants' invention to perform equally well with Gentelia's valve assembly with axles offset to the side because the intended use of forming a zero seal and an instrument seal is still possible with the valve assembly of Gentelia '714. Applicants respectfully traverse this rejection.

Claim 8 depends from Claim 7, which in turn depends from Claim 1. Claim 1 includes the roller having properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Applicants respectfully submit, as stated above, that Gentelia '714 fails to teach the rollers having properties for forming an instrument seal in the presence of the instrument.

Based on the foregoing, Applicants respectfully submit that Claim 8 is allowable over Gentelia '714 as depending from allowable Claims 1 and 7. Additionally, Applicants respectfully request that this rejection be reconsidered and removed.

Claims 9, 21 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gentelia '714 in view of U.S. Patent No. 5,599,348 to Gentelia, et al. (Gentelia '348). In the Office action it is indicated that Gentelia '714 discloses the invention substantially as claimed above and further discloses the roller (6 or 7) is sized and configured to form the instrument seal (FIG. 1) with the instrument seals of zero

diameter (FIG. 4) and small and larger diameter (col. 3, lines 21-35), but fails to specifically disclose the size of the instrument. It is further indicated in the Office action that Gentelia `348 teaches instrument seals of varying sizes and an upper limit in a range between about six millimeters and twelve millimeters, and the diameter of the instrument capable of being at least about five millimeters or ten millimeters (col. 4, lines 24-42). Additionally, it is indicated in the Office action that, therefore, it would have been obvious to a person of ordinary skill in the art to modify the valve seal assembly disclosed by Gentelia `714 to include instrument seals of particular sizes in the upper range of six to twelve millimeters, as taught by Gentelia `348 and that such a modification would allow the trocar to accommodate different sized instruments. Applicants respectfully traverse this rejection.

Claim 9 depends from Claim 1. As indicated above, independent Claim 1 is allowable over Gentelia `714 as having a roller that has properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument, and Applicants respectfully submit that Gentelia `348 does nothing to correct this deficiency. Based on the foregoing, Applicants respectfully submit that neither Gentelia `714 nor Gentelia `348, either alone or in combination, teaches the elements of Claim 9, and that Claim 9 is allowable over Gentelia `714 in view of Gentelia `348. Applicants further respectfully submit that Claim 9 is also allowable as depending from an allowable independent claim and respectfully request that this rejection be reconsidered and removed.

Claim 21 depends from Claim 15 and Claim 22 depends from Claim 21. As indicated above, independent Claim 15 is allowable over Gentelia `714 as having a

roller that is sized and configured to form a zero seal in the absence of an instrument and an instrument seal in the presence of the instrument, and Applicants respectfully submit that Gentelia `348 does nothing to correct this deficiency. Based on the foregoing, Applicants respectfully submit that neither Gentelia `714 nor Gentelia `348, either alone or in combination, teaches the elements of Claims 21 and 22, and that Claims 21 and 22 are allowable over Gentelia `714 in view of Gentelia `348. Applicants further respectfully submit that Claims 21 and 22 are also allowable as depending from an allowable independent claim and respectfully request that this rejection be reconsidered and removed.

Claims 16, 19, 20, 24, 25 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gentelia `714 in view of U.S. Patent No. 5,429,609 to Yoon (Yoon `609). Regarding Claims 16, 19 and 20, it is indicated in the Office action that Gentelia `714 discloses a roller supported on the axle and rotatable with the axle relative to the seal housing, wherein the axle has a fixed relationship with the seal housing (col. 2, line 53). It is further indicated in the Office action that Gentelia `714 fails to disclose the roller having a gel material, but that Yoon `609 teaches a valve assembly made of a compliant material (col. 6, lines 3-5), such as a gel material (col. 6, lines 11-15). It is also indicated in the Office action that it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the valve assembly disclosed by Gentelia `714 to include rollers made of gel as taught by Yoon `609. Applicants respectfully traverse this rejection.

Claim 16 depends from Claim 15 and Claims 19 and 20 depend from Claim 17, which depends from Claim 15. As indicated above, independent Claim 15 is allowable

over Gentelia `714 as having a roller that is sized and configured to form a zero seal in the absence of an instrument and an instrument seal in the presence of the instrument, and Applicants respectfully submit that Yoon `609 does nothing to correct this deficiency. Based on the foregoing, Applicants respectfully submit that neither Gentelia `714 nor Yoon `609, either alone or in combination, teaches the elements of Claims 16, 19 and 20, and that Claims 16, 19 and 20 are allowable over Gentelia `714 in view of Yoon `609. Applicants further respectfully submit that Claims 16, 19 and 20 are also allowable as depending from an allowable independent claim and respectfully request that this rejection be reconsidered and removed.

Regarding Claim 24, it is indicated in the Office action that Gentelia `714 discloses a cannula (3) extending along an axis between a proximal end and a distal end; a seal housing (2) communicating with the cannula to define a working channel (14); a roller (6 or 7) disposed within the seal housing, the roller being pivotal on an axis (10 or 11); and the roller being moveable by the inserted instrument to pivot the resilient material relative to the axis to inhibit tearing of the resilient material (FIGS. 1-4; col. 1, lines 57-61). Regarding Claim 25, it is indicated in the Office action that the roller has an end surface (contact surface between the two rollers; FIG. 4) and a circumferential surface (contact surface between rollers and inside surface 13); and an instrument (5) inserted into the working channel encounters a frictional resistance associated with the end surface (5 is frictionally in contact with end surface of rollers) and a rolling resistance associated with the circumferential surface (surface 13 against rollers provides a rotational resistance). Regarding Claim 31, it is indicated in the Office action that Gentelia `714 discloses the roller is a first roller (6), the axis is a first axis (10), and

the trocar assembly further comprises: a second roller (7) disposed within the seal housing (2) and being pivotal on a second axis (11) different than the first axis. It is acknowledged in the Office action that Gentelia '714 fails to disclose the roller having a compliant material such as a gel material and a resilient material included in the roller and having properties susceptible to tearing in response to an instrument inserted into the working channel. It is indicated in the Office action that Yoon '609 teaches the valve assembly to be made of a compliant material (col. 6, lines 3-5) such as gel material (col. 6, lines 11-15) that is susceptible to tearing (col. 6, lines 5-10) and that it, therefore, would have been obvious to a person of ordinary skill in the art, at the time of the invention, to modify the valve assembly disclosed by Gentelia '714 to include rollers made of gel as taught by Yoon '609. Additionally, it is indicated in the Office action that such a modification would allow more flexibility and range on instruments that can be used with the sealing apparatus. Applicants respectfully traverse this rejection.

Amended independent Claim 24 includes the resilient material providing the roller with properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Similar to above, Gentelia '714 fails to teach a roller including a resilient material that provides the roller with properties for forming a zero seal in the absence of the instrument and an instrument seal in the presence of the instrument. Applicants respectfully submit that Yoon '609 does nothing to correct this deficiency. Based on the foregoing, Applicants respectfully submit that neither Gentelia '714 nor Yoon '609, either alone or in combination, teaches the elements of amended Claim 24, and that Claim 24 is allowable over Gentelia '714 in

view of Yoon '609. Applicants respectfully request that this rejection be reconsidered and removed.

Claims 25 and 31 depend from Claim 24. As such, Applicants respectfully submit that neither Gentelia '714 nor Yoon '609, either alone or in combination, teaches the elements of Claims 25 and 31, and that Claims 25 and 31 are allowable over Gentelia '714 in view of Yoon '609. Applicants further respectfully submit that Claims 25 and 31 are also allowable as depending from an allowable independent claim and respectfully request that this rejection be reconsidered and removed.

Claims 47, 48, 54 and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gentelia '714 in view of Gentelia '348 and further in view of Yoon '609. It is indicated in the Office action that Gentelia '714 discloses a trocar assembly that includes a cannula (3) having an axis extending between a proximal end and a distal end; a valve housing (2) communicating with the cannula to define a working channel (14); a roller valve (6 or 7) disposed on an axle (10 or 11) in the valve housing, the valve having properties for forming a zero seal across the working channel in the absence of the instrument (FIG. 4), and an instrument seal across the working channel in the presence of the instrument (FIG. 1); wherein the valve comprises: first portions forming a wall seal with the valve housing (wall seal between roller and surface of 13); and second portions forming the zero seal in the absence of the instrument in the working channel (FIG. 4), and the instrument seal in the presence of the instrument in the working channel (FIG. 1); and Gentelia '348 discloses the instrument seal having a diameter in radial cross-section ranging from a lower limit of about zero millimeters to an upper limit greater than about six millimeters (FIG. 6; col. 4, lines 24-42). It is

acknowledged in the Office action that Gentelia `714, in view of Gentelia `348, fails to disclose a roller valve including a compliant material, wherein the compliant material includes a gel and includes an inflatable bladder. It is also indicated in the Office action that Yoon `609 teaches a valve assembly having a compliant material, including a gel and an inflatable bladder (FIG. 36; col. 6, lines 11-15). It is further indicated in the Office action that it would have been obvious to a person of ordinary skill in the art, at the time of the invention, to modify the valve assembly disclosed by Gentelia to include rollers made of gel as taught by Yoon `609, and that such a modification would allow more flexibility and range on instruments that can be used with the sealing apparatus. Applicants respectfully traverse this rejection.

The trocar assembly of Claim 47 of the present Application includes a roller valve disposed on an axle in the valve housing. The roller valve includes a compliant material and has properties for forming a zero seal across the working channel in the absence of the instrument and an instrument seal across the working channel in the presence of the instrument. Applicants respectfully submit that Gentelia `714 fails to teach a roller valve including a resilient material that provides the roller valve with properties for forming a zero seal across the working channel in the absence of the instrument and an instrument seal across the working channel in the presence of the instrument.

Applicants respectfully submit that Gentelia `348 and Yoon `609 do nothing to correct this deficiency. Based on the foregoing, Applicants respectfully submit that none of Gentelia `714, Gentelia `348 and Yoon `609, either alone or in combination, teaches the elements of Claim 47, and that Claim 47 is allowable over Gentelia `714 in view of

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Amendment Dated August 22, 2007
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Gentelia `348 and Yoon `609. Applicants respectfully request that this rejection be reconsidered and removed.

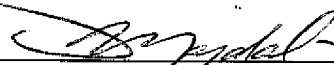
Claims 48, 54 and 55 depend from Claim 47. As such, Applicants respectfully submit that none of Gentelia `714, Gentelia `348 and Yoon `609, either alone or in combination, teaches the elements of Claims 48, 54 and 55, and that Claims 48, 54 and 55 are allowable over Gentelia `714 in view of Gentelia `348 and Yoon `609. Applicants further respectfully submit that Claims 48, 54 and 55 are also allowable as depending from an allowable independent claim and respectfully request that this rejection be reconsidered and removed.

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner believes that a telephone conference with Applicant's attorney might expedite prosecution of the Application, the Examiner is invited to call at the telephone number indicated below.

Sincerely

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